

MAY 18 2004

Traditional 510(k)  
Vaxcel™ Plus Chronic Dialysis Catheter  
March 19, 2004

## Summary of Safety and Effectiveness

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

### General Information

**Submitter:** Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760  
508-652-5003

**Contact Person:** Nicholas Condakes

### General Provisions

**Trade Name:** Vaxcel™ Plus Chronic Dialysis Catheter

**Classification Name:** Catheter and Tunneler , Hemodialysis

### Name of Predicate Devices

Vaxcel™ Plus Chronic Dialysis Catheter  
Medcomp Split cath II  
Bard Hickman catheter

### Classification

Class III

### Performance Standards

Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act

### Intended Use and Device Description

The Vaxcel™ Plus Chronic Dialysis Catheter is designed for chronic hemodialysis and apheresis. Catheter lengths of 37 cm and 50 cm are indicated for femoral vein insertion. The major components of the Vaxcel™ Plus Dialysis Catheter are the dual lumen catheter, dead end cap, introducer sheath/dilator, tunneler and CSR wrap.

### Summary of Substantial Equivalence

The Vaxcel™ Plus Chronic Dialysis Catheter and tunneler have been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 18 2004

Mr. Nicholas Condakes  
Regulatory Affairs Specialist  
Boston Scientific Corporation  
One Boston Scientific Place  
NATICK MA 01760-1573

Re: K040736

Trade/Device Name: Vaxcel™ Plus Chronic Dialysis Catheter  
Regulation Number: 21 CFR §876.5540  
Regulation Name: Blood access device and accessories  
Regulatory Class: III  
Product Code: 78 MSD  
Dated: March 19, 2004  
Received: March 22, 2004

Dear Mr. Condakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications For Use

510(k)  
Number  
(if known)

K040736

Device Name:

Vaxcel™ Plus Chronic Dialysis Catheter

Indications  
for Use

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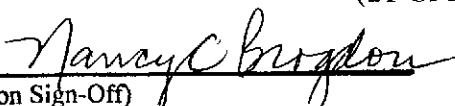
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

Confidential  
Boston Scientific Corporation

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K040736